

**Rejection of Claims Under 35 U.S.C. 102**

Claims 1 is rejected under 35 USC §102 as being anticipated by Leigh US Patent 5,141,674 (Leigh), which discloses "another grade of partially purified lecithin (Lipid II)." In response, Applicants have cancelled Claim 1.

**Rejection of Claims Under 35 U.S.C. 112**

Claims 13-24 stand rejected under 35 USC §112, second paragraph, as being incomplete for omitting "essential steps," i.e., "all of the steps necessary to isolate Lipid II." (emphasis added)

As stated by the court in *Clinical Products Limited v Brenner, Comr. Pats.*, 149 USPQ 475, 476 (DC DC 1966):

The second paragraph of 35 USC §112 does not read in terms of claiming subject matter which the Patent Office or Courts regard as an applicant's invention, but rather in terms of "claiming subject matter which the applicant regards as the invention," which provides considerable leeway to the applicant, if and provided that his claims include all truly essential limitations and to not utilize vague and ambiguous terms.

Applicants assert that the only essential step for Claims 13-24 is isolating the Lipid II at a pH greater than 6. The basis for this aspect of Applicant's invention is the discovery that the pyrophosphate moiety decomposes at pHs commonly employed in the art:

Decomposition of the Lipid II intermediate due to the acid sensitivity of the pyrophosphate group has not been fully recognized in the art. Applicants discovered that once the pyrophosphate moiety was present in the compound by-products from decomposition could be minimized by maintaining a pH greater than about 6. Preferably the pH is maintained from 6 to 12, more preferably from 7 to 10, even more preferably from 7 to 9.

(specification at p. 34, line 24 to p. 35, line 5).

Applicants further assert that Claims 13-24 are not limited to isolation of synthetic Lipid II. Rather, these claims are also directed to isolation of the natural product:

It is believed that even the natural product could be isolated in higher yields and purity if the pH was maintained at a pH greater than 6 instead of the current practice of using 6M pyridinium/acetate in the isolation procedure which has a pH

of 4.2. For a detailed description of the current isolation procedures for the natural product, see: Van Heuenoort, Y., et al., "Membrane Intermediates in the Peptidoglycan Metabolism of *Escherichia coli*: Possible Roles of PBP 1b and PBP 3," J. Bacteriol., 174(11), 3549-3557 (1992); and Anderson, J.S., et al., "Biosynthesis of the Peptidoglycan of Bacterial Cell Walls," J. Biol. Chem., 242(13), 3180-3190 (1967).

(specification at p. 35, lines 5-17).

Since Lipid II may be purified using conventional chromatography procedures well-known to those skilled in the art (see, e.g., specification p. 35, lines 18-20), these additional isolation steps are non-essential for patentability purposes. However, because Applicants have used the term "comprising" as the transitional phrase in Claims 13-24, additional isolation steps are clearly not excluded. See *Phillips Petroleum Co. v Huntsman Polymers Corp.*, 48 USPQ2d 1161, 1167 (Fed. Cir. 1998) ("The use of... 'which comprises' in the composition and process claims generally would mean that the claims require [the recited limitations], but that additional elements or process steps may be present."); *Genentech, Inc. v Chiron Corp.*, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (" 'Comprising' is a term of art used in claim language which means that the named elements are essential, but that other elements may be added and still form a construct within the scope of the claim").

In view of the foregoing, withdrawal of the present rejection is believed to be in order and such action is respectfully requested.

#### OVERALL SUMMARY AND CONCLUSIONS

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims set forth an invention that is new, useful, and unobvious, and which is therefore deserving of patent protection. Passage to Issue of the present application is believed to be in order, and is respectfully requested.

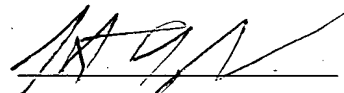
For the Examiner's convenience, a clean claim set is attached.

Serial No: 09/833,647

Please charge any fees or credit any overpayment in connection with this application which may be required by this or any related paper to Deposit Account No. 05-0840.

If the Examiner has any questions, or would like to discuss any matters in connection with this application, he or she is invited to contact the undersigned at (317) 276-0307.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'JAC', is written over a horizontal line.

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